Food Safety Legislation

Elizabeth Barr Fawell

October 14, 2009







Agenda

- How we got here
- Overview of H.R. 2749 The Food Safety Enhancement Act of 2009
 - New responsibilities for companies
 - Increased oversight of imports
 - New enforcement authorities
 - Fees
- What's next
- Key Differences in S. 510



How We Got Here

- Series of high profile food safety outbreaks
- Food manufacturing standards in the FFDCA date back to 1906
- Strong support from the Obama Administration



| | | US ADMINISTRATION | N UT REPERSY |
|--|--|--|--|
| 60 Eighth Street NE | | | /09/2009 - 01/27/2009* |
| Atlanta, GA 30309 | | FUER | Area Area area area area area area area |
| (404) 253-1161 Fax: (404) 253-1202 | | | 36857 |
| Industry Info | station: www.fds.gov/oc/ind | ustry | |
| | Lightsey, Plant Operations | | |
| Peanut Corporation Of America 14075 b | | 14075 Magnolia | St |
| Blakely, GA | | | |
| observations, and do observation, or have action with the FDA | observations made by the FDA representative() nor represent a final Agency determination re- implemented, or plan to implement, corrective representative(s) during the importion or sub- nant FDA at the phone number and address ab- | pardleg your compliance. It action in response to an of nit this information to FDA | I you have an objection regarding an beervation, you may discuss the objection or |
| DURING AN INSPEC | CTION OF YOUR FIRM WE OBSERVED: | | |
| OBSERVATION | 1 | | |
| Failure to magufac and contamination | ture foods under conditions and controls : | necessary to minimize th | n potential for growth of microorganism |
| Specifically, the fi | irm's own internal microbiological testing | found the following: | Alexan |
| | | | |
| b. totes of roasted the following prod butter under lot # 8 | reduct in interstate commerce. Additional peanuts received on 9(25/08. The lots of ucts that were also shipped in interstate or 1276: one tote was used to manufacture set | sted the product and reco ly, this peanut paste was reasted peanuts received ansmerce.(D)(B)(the were | on 9/25/08 were also used to produce |
| (b)(4) b. of the pr b. totes of reasted the following prod butter under lot # 8 (b)(4) andre lot # 1 Salmonalia Amatur | roduct in interstate commerce. Additional pearants received on 9(25/08. The lots of ucts that were alive shipped in interstate or 12/26 can tote was used to manufacture pe 52/77. In: Pearant Butter manufactured on 8/11/20 to laboratory. After the firm reteated to p | sted the product and received (a), this peaks was reasted peaks received manerece. (2020) or way assut butter for assut butter for 8 woder lot # 8220 and # | ebed a sugative status, the furn thisped manufactured on 9/26/08 from (D)(4) (on 9/25/08 were also used to produce used to manufacture (D)(4) cannot (D)(4) cannot (D)(4) cannot (D)(4) cannot (D)(4) cannot (D)(4) cannot (D)(4) cannot (D)(4) cannot (D)(4) cannot (D)(4) |
| (D)((2))c. of the particular the following produces the following produces the following produces the following produces the following particular to the following particu | roduct in interstate commerce. Additional pearants received on 9(25/08. The lots of ucts that were alive shipped in interstate or 12/26 can tote was used to manufacture pe 52/77. In: Pearant Butter manufactured on 8/11/20 to laboratory. After the firm reteated to p | sind the product and reco ly, this pream paste was reasted peaked to recover summerce (2015) ones were anot butter lost 8 moder lost # 8220 and # product and received a n regular manufactured on | ebed a megative status, the furn shipped manufactured on 9/26/08 from (D)(4) 4 on 9/25/08 were also used to module used to marafacture (D)(4) made lol # 5277 and (D)(4) 8224 tested positive for Salmonalla egative status, the product was shipped is September 24, 2008 under lot # \$268 |
| (D)(4))a, of the p (b), tote of roasted the following prod- builter under lot # 6 (D)(4) and the following pro- salmonella Arature salmonella Arature salmonella Arature tested positive for i statumental (no stru- salmonella (no stru | reduct in laterstate commerce. Additional pearants received on 9(25/08. The lots of ucts that were also shipped in interative or 12/26 can tote was used to manufacture pe 52/77. In: Pearant Hutter manufactured on 8/11/20 in laboratory. After the firm retested the 1 haberatory. After the firm retested the 1 on. Pearant Menal and Modivan Chopped Or Salmosella Anatum by a private laborator was shipped in interate commerce. in identified? Medium Chopped Oranula private laboratory. After the firm retest | sind the product and near by, this percent paste was received peakers received connerce. (1975) these were arrat batter for arrat batter for 8 moder lot # 8220 and # product and received a m received and received an received and received an results manufactured on y. After the firm retented a manufactured on June | ebed a segative status, the furn shipped manufactured on 9/26/08 from (10/4) (on 9/25/08 were also used to produce used to manufacture (10/4) essant (10/4) |
| (D)(D)) is of the pipeline of reased in totes of reased butter under lot a 3 (D)(D) and reases and the pipeline (D)(D) and reases and the pipeline (D)(D)(D)(D)(D)(D)(D)(D)(D)(D)(D)(D)(D)(| roduct in latienstate commerce. Additional pearants received on 9(25/08. The lets of ucts that were alive shipped in internate of 23/26 coat tote was used to manufacture pe 23/27. The second barries of the second second in laboratory. After the firm retested the y re. Pearant Meral and Modiven Chopped Ge Salmonella Anatem by a private inborator was shipped in internate commerce. ain identifiedly Medium Chopped Grassule a perivate laboratory. After the firm retested is commerce. ain identifiedly Sanall Chopped Orseales a visate laboratory. After the firm retested is commerce. | sind the product and near by, this peaks passes was created peakers received connected (CAS) and # annut below for the second and the second s | elved a megative status, the furn shipped manufarmered on 976-968 storm (D)(4) ton 9/25/08 were also und to module under to marinfacture (D)(4) made to marinfacture (D)(4) made to B 52/7 and (D)(4) 8224 tested positive for Salmonalla egative status, the product was shipped is September 24, 2008 under lot # 3268 9 the product and seceived a negative 16, 2008 under lot # 3163 tested positive ed a megative status, the product was 2008 under lot # 3161 tested positive for a negative status, the product was shipped |
| (D)(D)) is of the pipeline of reased in total of reased the following producting producting producting producting the following reads of the pipeline of the p | roduct in interstate commerce. Additional pearants received on 9/25/08. The less of ucts that were alive shipped in interstate of 2176; can tote was used to manufacture pe 2177. The Pearant Musiler manufacture of 8/11/0 in laboratory. After the firm retested the p 4. Tr. Pearant Meral and Modiven Chopped Gr Salmooella Anatara by a private laborator was shipped in interstate commerce. ain identified): Medium Chopped Gazzule a private laborator. After the firm retestes is commerce. | sind the product and peo- by, this persuit paster was reasted people received memories (2020)etes were annot butter for the 8 under lost \$ \$220 and \$ perduct and received a n results manufactured on y. After the firm retested a manufactured on June d the product and received a unsuffectured on June 9, e product and received a t | ebed a megnitive status, the furn shieped manufactured on 9/26/08 from (10/43) (on 9/25/08 were also used to produce used to manufacture (10/43) beam (10/44) model to 8 52/77 and (10/44) 8224 tested positive for Salmonalla rgative status, the product was shipped in September 24, 2008 under lot # 8263 the product and received a negative 16, 2008 under lot # 8163 tested positive ed a megnitive status, the product was 2008 under lot # 8161 tested positive for a megnitive status, the product was |



What's Coming

- July 2009, the U.S. House of Representatives passed H.R. 2749, the Food Safety Enhancement Act of 2009
 - New responsibilities for companies
 - Increased oversight of imports
 - New enforcement authorities
 - Fees



Food Industry Responsibilities



- Food Safety Plans
- Food Defense Plans
- Performance standards
- Full records access
- Traceability
- Reporting requirements
- Not to be forgotten
 - Annual registration
 - Risk-based inspections
 - Safety standards for fruits, vegetables, and nuts



To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food in the global market, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 8, 2009

Mr. DINGHLL (for himself, Mr. WAXMAN, Mr. PALLONE, Mr. STUFAR, Ms. DEGerrer, and Ms. SUTTON) introduced the following bill which was referred to the Committee on Energy and Commerce

A BILL

- To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food in the global market, and for other purposes.
- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Food Safety Enhance-
- 5 ment Act of 2009".
- 6 SEC. 2. TABLE OF CONTENTS.
- 7 The table of contents of this Act is as follows:
 - Sec. 1. Short title.
- Sec. 2. Table of contents. Sec. 3. References.
- Sec. 4. Rule of construction

- COOL

HOGAN &

HARTSON

I



Food Safety Plans

- Conduct hazard analysis
- Identify and implement preventive controls
 - To prevent, eliminate, or reduce hazards to an acceptable level
 - Those controls a person knowledgeable about safe manufacturing, processing, packing, transporting, holding of food would employ
 - Consistent with current scientific understanding
- Validate food safety plan
- Monitor and verify performance
- Take corrective and preventive actions as needed
- Keep records
- FDA can establish preventive controls by product type

Food Defense Plans



- Identify hazards that may be intentionally introduced
- Implement preventive measures to minimize risk of intentional contamination
 - Processing security
 - Cybersecurity
 - Material security (ingredients, finished product, packaging)
 - Personnel security
 - Storage security
 - Shipping and receiving security
 - Utility security
- Check that measures are in place and working; periodically test plan
- Maintain records of checks, corrective actions, assessment activities

Oversight of Imports

- Foreign facilities subject to all the same requirements as U.Sbased facilities
- FDA authority to require third party certification for food safetyrelated reason
- Accredited laboratory must be used for import testing
- Importers and customs brokers required to register
- Good importer practices
 - Including supply chain verification procedures
- Tighter control over import entry filings
- Expedited entry at border if safety and security guidelines met





Enforcement Authorities

- Civil money penalties
- Increased criminal penalties
- Suspension of registration
- Mandatory recall
- Quarantine
- Expanded administrative detention authority
- Subpoena power
- Prohibition on false or misleading reports
- Prohibition on delaying or refusing an inspection







© 2009 Hogan & Hartson LLP. All rights reserved.

Fees

- Registration Fee
 - \$500 per facility
 - \$175,000 cap per company
- Registration fee for importers (but not customs brokers)
 - \$500
- Reimbursement to FDA for
 - Re-inspections
 - Recall
- Export certificates







Next Steps

- · Senate expected to take up a bill this fall
- President Obama will likely sign



How Does a Bill Become a Law?



© 2009 Hogan & Hartson LLP. All rights reserved.

Key Differences in S. 510

- Traceability
- Records Access
- Mandatory recall authority
- Foreign supplier verification program
- Third party certification
- No registration fee
- Fewer enforcement authorities
- No COOL

111TH CONGRESS 1ST SESSION

> To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

S. 510

IN THE SENATE OF THE UNITED STATES

MANCH 3, 2009

Mr. DURISIN (for himself, Mr. GREGG, Mr. KRENNEDY, Mr. BURE, Mr. DODD, Mr. ALEXANDERS, and Mr. ISANSCOO) introduced the following bill, which was read twice and referred to the Committee on Health, Education, Labor, and Persions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

1 Be it enacted by the Senate and House of Representa-

2 tives of the United States of America in Congress assembled,

3 SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CON-

TENTS.

4

5 (a) SHORT TITLE.—This Act may be cited as the

6 "FDA Food Safety Modernization Act".

7 (b) REFERENCES.—Except as otherwise specified,

8 whenever in this Act an amendment is expressed in terms

9 of an amendment to a section or other provision, the ref-



п

© 2009 Hogan & Hartson LLP. All rights reserved.

Down the Road

- Various effective dates for different provisions
- Some provisions require FDA fact-finding and new regulations
- Longer implementation time for small and very small **businesses**







HOGAN & HARTSON

For more information on Hogan & Hartson, please visit us at

www.hhlaw.com

Abu Dhabi Baltimore Beijing Berlin Boulder Brussels Caracas Colorado Springs Denver Geneva Hong Kong Houston London Los Angeles Miami Moscow Munich New York Northern Virginia Paris Philadelphia San Francisco Shanghai Silicon Valley Tokyo Warsaw Washington, DC

© 2009 Hogan & Hartson LLP. All rights reserved.